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10/680,366	10/06/2003	Jeffrey A. Nielsen	200310347	4652

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EXAMINER	
LAMBELET, LAWRENCE EMILE	
ART UNIT	**PAPER NUMBER**
1732	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	**Application No.** 10/680,366	**Applicant(s)** NIELSEN ET AL.	
	Examiner Lawrence Lambelet	**Art Unit** 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28 and 47-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28 and 47-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of claims 1-28 in the reply filed on 11/14/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). New claims 47-49 will be grouped with the elected invention.

Response to Amendment

Applicant's amendment filed on 11/14/2006 is acknowledged. Cancelled claims 29-46, amended claims 1, 4-7, 9 and 21, and new claims 47-49 are placed of record in the file. The objections to drawings and the specification are withdrawn in view of amendment. Claims 1-28 and 47-49 are currently actionable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 15-20 and 48-49 are rejected under 35 U.S.C. 102(e) as being anticipated by Czernuszka et al (U.S. Patent Publication 2004/0258729).

Czernuszka et al, hereafter "Czernuszka", discloses a method of producing porous structures with SFF, as recited in claim 15. Czernuszka teaches depositing molten micro droplets (rapidly solidifying build material) to form a porous structure coupled by overlapping beads. This is shown in paragraphs [0007] and [0009] to [0011].

Czernuszka teaches disposing a property enhancing material, namely a collagen scaffolding (flexible), in the mold (porous configuration), as required by claims 16 and 17. Appropriate citation can be found in paragraph [0018].

Czernuszka teaches overhanging structure of the build material, as required by claim 18, in paragraph [0011].

Czernuszka teaches repeating layer depositions to form a 3D structure in paragraph [0011]. Such a structure would inherently have vertical and planar arrays of voxels, as required by claims 19 and 20.

Czernuszka teaches 3D Printing as an SFF technique. See paragraph [0009]. It is well known in the art that 3D Printing includes an apparatus component to receive a selective deposition of material, such as a fabrication bin, as well as a print head receiving operational instructions from a computer-aided design model, wherein a pattern is defined, as required by claim 48.

Czernuszka teaches that channels and pores are built in a scaffold structure (multi-layered), as required by claim 49. See paragraph [0009].

Claims 21-26 are rejected under 35 U.S.C. 102(e) as being anticipated by Taboas et al (U.S. Patent Publication 2003/0006534)

Taboas et al, hereafter "Taboas", discloses a method of producing porous structures with SFF, as recited in claim 21. Taboas teaches fabrication of a mold (coupled containment structures) having porous regions and casting a material within (bulk build material). This is shown in paragraphs [0054], [0058], and [0065].

Taboas teaches forming the mold with 3D Printing, a method using ink jet drop-on-demand technology (high precision dispenser), as required by claim 22, and as shown in paragraph [0058]. It is known that this technology selectively deposits voxels in a layer configuration and builds successive layers into a 3D object. Vertical and planar arrays of voxels, as required by claims 23 and 24, are thus inherent in such a scheme. Inevitably, in such arrays, a bridging voxel will occur, such that a porous gap is spanned, as required by claim 26.

Taboas teaches that the build material is cast in paragraph [0065]. Casting, as opposed to printing, implies a low precision material dispenser, as required by claim 25.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 10-11, 13-14 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monkhouse et al (W.O. Publication 00/29202).

Monkhouse et al, hereafter "Monkhouse", discloses a method of producing porous structures with solid freeform fabrication (SFF), as recited in claims 1 and 14. Monkhouse teaches selectively depositing a water-soluble material (removable support) prior to depositing a pattern of binder onto an insoluble layer (build material), and subsequently dissolving the first material to produce controlled pores or channels. This is shown at lines 7-10 on page 14, 23-30 on page 15, and 1-4 on page 16.

Monkhouse teaches a dosage form having active and placebo ingredient regions produced by an SFF method at line 39 on page 12 and lines 1-3 on page 13. The placebo performs a non-removable support material function, as required by claim 2, in that it effectively isolates space within an active ingredient matrix.

Monkhouse teaches planarizing layers, as required by claim 3, and as found at lines 19-23 on page 9 with illustration in Fig. 1.

Monkhouse teaches means of solidifying a deposition (build material), including heating and curing, as required by claims 1, 4 and 5. This is shown at lines 9-14 on page 11.

Monkhouse teaches that the insoluble material (build) follows the soluble (support) in order of preparation steps, as required by claim 6, and as shown at lines 23-25 on page 15.

Monkhouse teaches selective deposition of materials by 3D Printing (high-precision dispenser), as required by claim 13. Appropriate citation can be found at lines

22-29 on page 7 and 3-7 on page 8. The precision resides in a drop-on-demand print head.

Monkhouse teaches a staggering of microarchitectural channels throughout a device prepared in the manner of claim 1 above at lines 5-12 on page 16. This suggests voxels in both planar and vertical arrays, as required by claims 10 and 11.

Monkhouse teaches that build and support material are dispensed as a moving stage traverses a fabrication bin, as required by claim 47. This is shown in Fig. 1, where reference number 28 is the fabrication bin and reference number 12 (feeder source not shown) is the moving stage.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the embodiment of tissue scaffolding with that of drug delivery. Both embodiments use the same SFF method and differ only in the aspect of properties of the materials used. Motivation to combine would have been to improve dissolution rate by adding porosity to structure. See lines 5-15 on page 7.

Claims 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monkhouse, as applied to claims 1-6, 10-11, 13-14 and 47 above, and further in view of Taboas.

Monkhouse teaches the method of claims 1-6, 10-11, 13-14 and 47, as discussed above.

Monkhouse teaches selective deposition of materials by 3D Printing (high-precision dispenser), as required by claim 9. Appropriate citation can be found at lines

22-29 on page 7 and 3-7 on page 8. The precision resides in a drop-on-demand print head

Monkhouse does not teach depositing build material with a low precision dispenser, as required by claims 9 and 12.

Taboas teaches that the build material is cast in paragraph [0065]. Casting, as opposed to printing, implies a low precision material dispenser.

Monkhouse and Taboas are combinable because they are concerned with a similar technical field, namely, scaffold fabrication. One of ordinary skill in the art at the time of the invention would have found it obvious to include in the method of Monkhouse the bulk deposition method, as taught by Taboas, and would have been motivated to do so avoid time-consuming discrete deposition.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Monkhouse, and further in view of Schmidt (U.S. Patent 6,228,437).

Monkhouse teaches selectively depositing a water-soluble material (removable support) prior to depositing a pattern of binder onto an insoluble layer (build material), and subsequently dissolving the first material to produce controlled pores or channels, as required by claim 7. This is shown at lines 7-10 on page 14, 23-30 on page 15, and 1-4 on page 16.

Monkhouse does not teach infiltrating pores with a property enhancing material, as also required by claim 7, or in specific terms, a material of high toughness, as required by claim 8.

Schmidt teaches infiltrating an SFF porous structure with a pre-ceramic polymer thereby enhancing the mechanical strength (toughness) of the structure. This is shown at lines 62-67 in column 2 and lines 1-13 in column 3.

Monkhouse and Schmidt are combinable because they are concerned with a similar technical field, namely, solid freeform fabrication . One of ordinary skill in the art at the time of the invention would have found it obvious to include in the method of Monkhouse the property enhancing technique of Schmidt, and would have been motivated to do so for robustness of structure.

Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taboas, as applied to claims 21-26 above, and further in view of Schmidt.

Taboas teaches the method of claims 21-26, as discussed above.

Taboas does not teach infiltrating pores with a property enhancing material, as required by claim 27, or specifically, a material of high toughness, as required by claim 28.

Schmidt teaches infiltrating an SFF porous structure with a pre-ceramic polymer thereby enhancing the mechanical strength (toughness) of the structure. This is shown at lines 62-67 in column 2 and lines 1-13 in column 3.

Taboas and Schmidt are combinable because they are concerned with a similar technical field, namely, solid freeform fabrication. One of ordinary skill in the art at the time of the invention would have found it obvious to include in the method of Taboas the property enhancing technique of Schmidt, and would have been motivated to do so for robustness of structure.

Response to Arguments

Applicant's arguments filed 11/14/2006 have been fully considered but they are not persuasive.

With regard to Monkhouse, applicant argues that the reference does not teach a curable build material or a selectively deposited removable support material. Applicant further argues that it is improper, when anticipation is cited, to combine a drug delivery embodiment with a tissue scaffolding embodiment. Applicant further argues that the powdered build material of Monkhouse is not flowable, as required by the claim recitation.

In response, the removable support material can be said to be selectively deposited, in that alternate materials can be selected for multiple powder layers. See lines 25-31 on page 9 and 1-8 on page 10. Furthermore, the build material acted upon by the binder is shown as a curable composite. See lines 9-14 on page 11. The powdered material is handled as a fluid material, and, as such, is flowable.

The argument with respect to anticipation is moot in view of a new case for prima facie obviousness over Monkhouse. It is well settled that a reference must be considered for not only what it expressly teaches, but also for what it fairly suggests and that the entirety of the reference disclosure, including unpreferred embodiments must be considered in determining obviousness. *In re Burckel* 592 F.2d 1175, 201 USPQ 67 (CCPA 1979; *In re Lamberti* 545 F.2d 192 USPQ 278 (CCPA 1976).

With regard to Czernuska, applicant argues that reference does not teach selectively depositing a build material. Applicant further argues that Czernuska does not teach disposing a property enhancing material in pores. Applicant still further argues that Czernuska teaches a mold and not a structure having a porous configuration. Applicant lastly argues that reference does not teach stacking voxels.

In response, the "mold" of Czernuska is a structure made by SFF with ink-jet print heads (selective depositing). The structure becomes porous after removal of support material. See paragraphs [0007], [0009] and [0011]. The material invested in the structure is collagen, which can be said to be property enhancing because it is chemotactic (cell-attracting). See paragraph [0018]. A voxel is simply a volume element which comprises the structure in stacks and arrays.

With regard to Taboas, Applicant argues that reference teaches use of a mold, not a plurality of support material containment structures formed by selective depositing of material by a material dispenser with bulk build material dispensed into intervening gaps.

In response, Taboas teaches that the "mold" is a structure made by SFF, which involves selective deposition of material from a dispensing head. See paragraph [0015]. The mold is formed from a deposit of two materials, one of which is removed to allow investment of a casting material (build material) before removal of the final sacrificial material. See paragraphs [0065] and [0088].

The use of the term "mold" is a choice of description and should not prejudice the attributes and features of the disclosed structures.

With regard to Monkhouse in view of Schmidt, applicant argues that it would not have been obvious to invest the tissue scaffolding structure of Monkhouse with the ceramic material as taught by Schmidt because it would destroy the intended use.

In response, a particulate ceramic material in the scaffolding voids could provide a microporous environment, which would be ideal for certain types of cell growth, in addition to providing structural strength. This would not be contrary to the intended function of the scaffold. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lawrence Lambelet whose telephone number is 571-272-1713. The examiner can normally be reached on 8 am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEL
2/3/2007

MARK EASHOO, PH.D
PRIMARY EXAMINER

04/Feb/07